

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 1-29, 31-33, 39, 55, and 57 were previously canceled.

Claims 30, 34-38, 40-43, 47-54, 56, 58 and 59 are amended to recite specific embodiments.

In particular, the claims are amended to recite “at least one piece of skin” instead of “at least one test membrane,” as supported throughout the specification as filed, including in paragraphs [0033] and [0094] and original claim 16. The claims also are amended to distinguish between “a first plurality of formulations” in the plurality of first wells and “a second plurality of formulations” in the plurality of second wells, as supported throughout the specification as filed.

Claim 30 also is amended to clarify aspects of the generally cylindrical plate channel in the first plate, as being positioned between the first and second ends of the first wells, as illustrated, for example, in Figure 5 and described in paragraphs [0108] and [0109] of the published application. Claim 30 also is amended to clarify aspects of the generally cylindrical rod in the plate channel in the first plate, as promoting contact of the first plurality of formulations with the at least one piece of skin, as described, for example, in paragraph [0109] of the published application. Conforming amendments are made to claims 34, 35, 40, 42, 56, 58 and 59.

Claims 36, 37, 48 and 49 are amended to clarify that the recited electrodes are for measuring electrical conductance or impedance of the at least one piece of skin, as described, for example, in paragraph [0144] of the published application.

Other conforming and clerical amendments are made to further clarify the claims.

Claim 60 is added to recite a specific embodiment of method claim 56, supported throughout the specification as filed and in the examples. Claims 61 and 62 are added to present the subject matter of previous claims 45 and 47 in independent claims.

Applicant respectfully requests entry of these amendments, which do not introduce new matter, and reconsideration of pending claims 30, 34-38, 40-54, 56, 58, and 59-62.

Allowable Subject Matter

Applicant notes with appreciation the indication that claims 45 and 47 would be allowable if rewritten in independent form. As noted above, claims 61 and 62 are independent claims corresponding to previous claims 45 and 47.

Telephonic Interview

Applicant thanks the Examiner for the courtesies extended during the Telephonic Interview on October 27, 2011. Applicant's Statement of the Substance of the Interview is provided here. The Examiner indicated that Applicant's proposed claim amendments (set forth above) and explanations of the cited references appeared to overcome the pending rejections. Applicant summarizes these points herein below.

The July 6, 2011 Office Action

Applicant notes with appreciation the indication that the rejections set forth in the previous Office Action have been overcome. Applicant addresses the new rejections below.

Claims 30, 34, 35, 40-44, 46, 51-54, 56, 58 and 59 are rejected under 35 USC § 103(a) as allegedly being unpatentable over Mansky (U.S. 6,455,007) in view of Mohan (U.S. 5,880,830). Claims 36-38 and 48-50 are rejected under 35 USC § 103(a) as allegedly being unpatentable over Mansky, Mohan and Pfost (U.S. 6,485,690). Applicant respectfully traverses these rejections.

As reflected in independent claim 40, the pending apparatus claims recite an apparatus for assaying effects of formulations on barrier properties of at least one piece of skin, comprising (i) a donor plate including a plurality of donor wells arranged in an array, each of

the donor wells including a first end sealable with the at least one piece of skin, and top openings at a second end through which a first plurality of formulations may be introduced or removed; (ii) a receptor plate mountable to the donor plate to sandwich the at least one piece of skin therebetween, the receptor plate including a plurality of receptor wells arranged in an array, each of the receptor wells including a first end sealable with the at least one piece of skin, and bottom openings at a second end through which a second plurality of formulations may be introduced or removed; and (iii) a sealing device configured to seal the top and bottom openings to retain the formulations in the donor and receptor wells and promotes contact between the formulations and the at least one piece of skin independently of an orientation of the apparatus. Independent claim 30 recites a similar apparatus with additional features. Independent claim 56 recites assay methods. The combination of Mansky and Mohan does not teach or suggest such apparatuses or methods.

Mansky describes an apparatus for use in testing fabric care chemicals such as anti-dye transfer polymers, dye absorbers, pretreatment agents, or stain guard agents. In the embodiments of Figures 1-2 and 4, the apparatus holds a piece of fabric between an upper plate (with a plurality of upper fluid chambers) and a central plate (with a plurality of central fluid chambers) or a lower plate (with a plurality of fluid cavities). A flexible membrane is disposed between the central and lower plates (or above the lower plate if the central plate is not present, see Fig. 1C) and is deflected mechanically or by vacuum to force fluid through the fabric and provide agitation. In the embodiment of Figure 6, only the central plate has fluid chambers. After the testing cycles are completed, the apparatus is disassembled to remove the fluid. See Mansky, col 11.

Mohan is directed to an apparatus for conducting multiple chemical reactions in a plurality of vessels mounted in inlets in a manifold block. The manifold block can be connected to different inlet and collection systems to carry out different steps of the chemical reaction, e.g., chemical reaction, washing, cleaving, collecting. The apparatus includes valve channels and rods that can be rotated to retain liquid or allow it to drain. See, e.g., Mohan, col. 11, lines 20-47.

The Office Action alleges that it would have been obvious to “add the valve feature from Mohan” to the device of Mansky, but this assertion overlooks many differences between the cited references, and still does not establish a *prima facie* case of obviousness.

I. Mohan is Non-Analogous Art

At the outset, Applicant questions whether Mohan even is analogous art to the claimed apparatuses and methods.

“Two separate tests define the scope of analogous prior art: (1) whether the art is from the same field of endeavor, regardless of the problem addressed and, (2) if the reference is not within the field of the inventor’s endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.” *In re Klein*, No. 2010-1411, slip op. at 7 (Fed. Cir. Jun. 6, 2011). MPEP § 2141.01(a). Mohan does not satisfy either prong of this test.

Mohan is not in the field of the claimed invention, because it relates to an apparatus for conducting multiple chemical reactions, such as required for solid phase chemical synthesis. Mohan does not address or solve the problem addressed by the claimed invention, e.g., providing an apparatus for assaying effects of formulations on barrier properties of a piece of skin, comprising a sealing device configured to seal top and bottom openings in donor and receptor wells to retain formulations in the donor and receptor wells and promote contact between the formulations and the at least one piece of skin independently of an orientation of the apparatus, let alone the recited methods.

“A reference qualifies as prior art for an obviousness determination under § 103 only when it is analogous to the claimed invention.” *Id.* Here, where Mohan does not satisfy either prong of the analogous art test, the rejection based on Mohan is improper and should be withdrawn.

II. Mansky Cannot Be Combined with Mohan in the Manner Asserted

Mansky and Mohan are directed to two completely different types of apparatuses. Mansky’s apparatus provides a means for applying multiple compositions to discrete

segments of a fabric sample, while Mohan's device provides a means for conducting multiple chemical reactions in series. Thus, Applicant questions whether a skilled artisan looking to practice or improve upon the methods and apparatuses of Mansky would have had any reason to look to the teachings of Mohan.

The Office Action proposes a combination of the valve channels and rods from Mohan with the device of Mansky, but there is no reason to provide valve channels and rods in Mansky. To the contrary, the goal of Mansky is to retain the fluid in contact with the fabric, and force the fluid to flow through the fabric. Mansky is not concerned with draining the fluid for a subsequent chemical reaction, which is the purpose of the valves in Mohan.

Applicant notes that the openings in Mansky's lower plate (e.g., element 22 of Fig. 1) extend only *partially* through the plate to form cavities (40). These cavities are interconnected with one another through passages (42) within the plate which in turn are connected to an inlet (46) *for applying pressure or vacuum* to the cavities. See Mansky, Figs. 1A, 2A, col. 6, lines 5-22. A *flexible membrane* (50) is *interposed between the lower and central plates* (22, 24) which deflects in response to the pressure or vacuum. In order to create fluid agitation, the fluid may be forced through the test regions (68) by applying a vacuum or pressure (or both) to the cavities below the flexible membrane. See Mansky, FIGS. 1A, 2A, col. 8, lines 15-60.

If the cavities of Mansky were sealed by the valve stem mechanism of Mohan, the fluid agitation method taught in Mansky would not be possible. The device of Mansky could not operate with the valve stem mechanism of Mohan, since this would create a closed system in which vacuum/pressure could not be applied to the flexible membrane, rendering it unsatisfactory for its intended purpose. Thus, the asserted combination of references is contrary to MPEP 2143.01, which provides that “[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.”

Additionally, this combination of references does not lead to the claimed apparatus, which permits formulations to be introduced through both a first plate and a second plate. For example, the flexible membrane of Mansky, which is formed of a nonporous material (see, e.g., Mansky, col. 9, lines 10-12), would block the introduction of formulations through its bottom plate.

III. The Cited References Do Not Teach An Apparatus With Two-Sided Introduction of Samples

Independent claim 40 recites an apparatus with (i) a donor plate including a plurality of donor wells with openings through which formulations may be introduced or removed and (ii) a receptor plate including a plurality of receptor wells with openings through which formulations may be introduced or removed, and independent claim 36 recites an apparatus with similar features. Neither Mansky nor Mohan even contemplate a two-sided introduction of samples.

As explained above, the passages (42) in Mansky's bottom plate are connected to an inlet for applying *pressure or vacuum* to the cavities, such as via the pneumatic circuit (100) shown in FIG. 5. Thus, these passages are not configured for the introduction of formulations. There is simply no teaching or suggestion in Mansky of introducing fluid to the cavities of the lower plate, either through the passages or otherwise.

Further, Mansky actually teaches away from a "two-way" introduction of fluids by relying on a flexible membrane to provide fluid agitation. The flexible membrane would block any liquid from the passages from reaching the porous sheet. Although the embodiment of Figure 6 may not include a flexible membrane (instead, other mechanisms are used to provide agitation, see, e.g., Mansky col. 10, lines 30-38), in that embodiment only the central plate includes fluid chambers. There is no lower plate with cavities and passages.

As explained previously, Mohan teaches only "one-way" flow of liquid through its apparatus, and relies on gravity or a vacuum to draw liquid out of the bottom of its reaction vessels.

Because the combination of Mansky with Mohan does not suggest the claimed invention as a whole, the rejection should be withdrawn.

IV. The Cited Reference Do Not Teach An Apparatus for Assaying the Affects of Formulations on the Barrier Properties of Skin

Independent method claim 56 recites a method of assaying effects of formulations on the barrier properties of skin, and independent apparatus claims 30 and 40 recite apparatuses for use in such a method. Neither Mansky nor Mohan teach or suggest such methods or apparatuses.

Mansky is directed to an apparatus for testing compositions on a porous medium, such as fabric. Mansky mentions a number of different properties that can be tested (e.g., stain resistance, wrinkling), but does not mention anything corresponding to a barrier property.

Mohan discloses an apparatus for performing multiple chemical reactions in a plurality of vessels, and does not relate in any way to assaying the effects of different formulations composition on any material, let alone skin.

V. Neither Reference Teaches an Apparatus That Can Be Inverted

Independent method claim 56 recites a method that includes inverting an orientation of the assembled donor and receptor plates, and independent apparatus claims 30 and 40 recite apparatuses for use in such a method. Neither Mansky nor Mohan even contemplate a device that can be inverted during use.

Mansky mentions at column 6, lines 1-4, that the position of the upper and lower plates may be switched, but this appears to describe an alternate *permanent* orientation of the apparatus, and does not teach or suggest that the apparatus as a whole can be inverted during use.

VI. Pfost Does Not Teach the Embodiments of Claims 36-38 and 48-50

Pfost was cited for teaching a device with electrical elements for heating. These embodiments of Pfost do not teach or suggest the embodiments of claims 36-38 and 48-50.

As shown above, the combination of Mansky and Mohan do not make out a prima facie case of obviousness of the independent claims. Combining these references with Pfost does not remedy their deficiencies. Moreover, Pfost does not even suggest the specific embodiments recited in these dependent claims.

As reflected above, instant claims 36 and 48 recite that the electrodes contact the formulation in the wells once the wells are filled, and are for measuring electrical conductance or impedance of the skin. Pfost's heating elements do not teach or suggest such an arrangement.

For at least these reasons, Applicant respectfully urges reconsideration and withdrawal of the pending § 103 rejections.

Conclusion

Applicant believes that the application is in condition for allowance, and an early notice to that effect is earnestly solicited.

Should there be any questions regarding this submission, or should any issue remain, the Examiner is invited to contact the undersigned by telephone to advance prosecution.

Respectfully submitted,

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